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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,586	03/31/2005	Mitsuo Honda	2005_0221A	6551
<div>513 7590 02/21/2008 WENDEROTH, LIND &amp; PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021</div>			<div>EXAMINER SWARTZ, RODNEY P</div>	
			<div>ART UNIT 1645</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 02/21/2008</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/524,586

Applicant(s)

HONDA ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 28 September 2007, is acknowledged. Claims 1 and 2 have been amended. New claim 3 has been added.
2. Claims 1-3 are pending and under consideration.

### **Objections/Rejections Withdrawn**

3. The objection to Figure 1 is withdrawn in light of the amendment of the specification.
4. The objection to Figure 2 is withdrawn in light of the amendment of the specification.
5. The objection to Figure 4C is withdrawn in light of the submitted substitute Figure 4C.
6. The objection to claim 1 is withdrawn in light of the amendment of the claim.
7. The rejection of claims 1 and 2 under 35 U.S.C. 112, second paragraph, indefiniteness for "without a change", is withdrawn in light of the amendment of the claims.
8. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, indefiniteness for "total positions" and "type", is withdrawn in light of the amendment of the claim.

### **Rejection Maintained**

9. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Bloom et al (U.S. Pat. No. 5,504,005) in light of Andersson et al (*Microbiology*, 142:915-925, 1996) is maintained.

Applicants argue that the amendment of the claims to recite that the polynucleotide is "artificially" modified obviates the rejection because neither reference teaches artificial modification of the polynucleotides.

The examiner has considered applicants' argument, but does not find it persuasive. The recitation of "artificially modified" is merely a process for obtaining a product. The claims are drawn to the product, i.e., a recombinant BCG transformed with an expression vector

comprising a polynucleotide encoding a foreign antigenic protein, wherein the polynucleotide has either a G or C without changing the amino acid sequence encoded by the polynucleotide.

As put forth in the original rejection, product is taught by the cited references, i.e., a recombinant BCG transformed with an expression vector comprising a G+C content at the third ending position of codons of 83%.

### **Claim Rejections - 35 USC § 112**

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 1 now recites that the third position of each codon is substituted with G or C without changing the "amino acid sequence encoded by the codon". It is unclear what is meant by a single codon encoding an entire sequence.

Newly amended claim 2 now recites that the first and second positions of each codon is further substituted with G or C without changing the "amino acid sequence encoded by the codon". It is unclear what is meant by a single codon encoding an entire sequence.

Claim 3 depends from either claim 1 or claim 2, but does not clarify the issues.

### **Conclusion**

12. Claims 1-3 remain rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

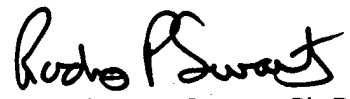
The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

February 13, 2008